

10802058 - GAU: 1615

Please type a plus sign (+) inside this box

PTO/SB/08A (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

|       |   |    |   |
|-------|---|----|---|
| Sheet | 1 | of | 4 |
|-------|---|----|---|

Complete if Known

|                      |                |
|----------------------|----------------|
| Application Number   | 10/802,058     |
| Filing Date          | March 17, 2004 |
| First Named Inventor | CHAUHAN, ANUJ  |
| Art Unit             | 1615           |
| Examiner Name        | HAGOPIAN, C.   |

|                        |                  |
|------------------------|------------------|
| Attorney Docket Number | T2315-908542US02 |
|------------------------|------------------|

## U.S. PATENT DOCUMENTS

[illegible]

## FOREIGN PATENT DOCUMENTS

[illegible]

|                       |                  |                    |            |
|-----------------------|------------------|--------------------|------------|
| Examiner<br>Signature | /Casey Hagopian/ | Date<br>Considered | 04/10/2008 |
|-----------------------|------------------|--------------------|------------|

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered.

Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard St.3). <sup>4</sup>

For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. This information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450**

Please type a plus sign (+) inside this box

PTO/SB/08A (08-03)

Approved for use through 07/31/2006. OMB 0651-0031  
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 2

of

4

Complete if Known

|                      |                |
|----------------------|----------------|
| Application Number   | 10/802,058     |
| Filing Date          | March 17, 2004 |
| First Named Inventor | CHAUHAN, ANUJ  |
| Art Unit             | 1615           |
| Examiner Name        | HAGOPIAN, C.   |

|                        |                  |
|------------------------|------------------|
| Attorney Docket Number | T2315-908542US02 |
|------------------------|------------------|

**OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS**

| Examiner Initials* | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T <sup>2</sup> |
|--------------------|-----------------------|---|----------------|
| /C.H./             |                       | Nagarsenker, M.S., Londhe, V.Y., Nadkarni, G.D., "Preparation and evaluation of liposomal formulations of tropicamide for ocular delivery", Int. J. of Pharm., 1990, 190: 63-71   | X              |
|                    |                       | Bourlais, C.L., Acar, L., Zia H., Sado, P.A., Needham, T., Leverage, R., "Ophthalmic drug delivery systems", Progress in retinal and eye research, 1998, 17, 1: 33-58   | X              |
|                    |                       | Lang, J.C., "Ocular drug delivery conventional ocular formulations". Adv. Drug Delivery, 1995, 16: 39-43  | X              |
|                    |                       | Segal, M., "Patches, pumps and timed release", FDA Consumer magazine, October 1991  | X              |
|                    |                       | Hehl, E.M., Beck, R., Luthard K., Guthoff R., "Improved penetration of aminoglycosides and fluoroquinolones into the aqueous humour of patients by means of Acuvue contact lenses", European Journal of Clinical Pharmacology, 1999, 55 (4): 317-323]           | X              |
|                    |                       | Hillman, J.S., "Management of acute glaucoma with Pilocarpine-soaked hydrophilic lens" Brit.J.Ophthal.58 (1974) p. 674-679  | X              |
|                    |                       | Ramer, R. and Gasset, A., "Ocular Penetration of Pilocarpine:" Ann.Ophthalmol.6, (1974) p. 1325-1327  | X              |
|                    |                       | Montague Ruben. and Watkins, R., "Pilocarpine dispensation for the soft hydrophilic contact lens" Brit.J.Ophthal. 59, (1975) p. 455-458   | X              |
|                    |                       | Hillman, J., Marsters, J. and Broad, A. "Pilocarpine delivery by hydrophilic lens in the management of acute glaucoma" Trans. Ophthal.Soc.U.K. (1975) p. 79-84  | X              |
| /C.H./             |                       | Giambattista, B., Virno, M., Pecori-Giraldi, Pellegrino, N. and Motolese, E. "Possibility of Isoproterenol Therapy with Soft Contact Lenses: Ocular Hypotension Without Systemic Effects" Ann.Ophthalmol 8 (1976) p. 819-829                                    | X              |

Examiner  
Signature

/Casey Hagopian/

Date  
Considered

04/10/2008

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard St.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. This information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



PTO/SB/08A (08-03)

Approved for use through 07/31/2006. OMB 0651-0031  
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

|   |                        |                      |                |
|---|------------------------|----------------------|----------------|
| Substitute for form 1449A/PTO   |                        | Complete if Known    |                |
| <b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br>(use as many sheets as necessary) |                        | Application Number   | 10/802,058     |
|   |                        | Filing Date          | March 17, 2004 |
|   |                        | First Named Inventor | CHAUHAN, ANUJ  |
|   |                        | Art Unit             | 1615           |
|   |                        | Examiner Name        | HAGOPIAN, C.   |
| Sheet 3 of 4  | Attorney Docket Number | T2315-908542US02     |                |

## OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

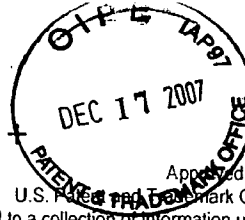
| Examiner Initials* | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T <sup>2</sup> |
|--------------------|-----------------------|---|----------------|
| /C.H./             |                       | Marmion, V.J. and Yardakul, S. "Pilocarpine administration by contact lens" Trans. Ophthal. Soc. U.K. 97, (1977) p. 162-3   | X              |
|                    |                       | Elisseeff, J., McIntosh, W., Anseth, K., Riley, S., Ragan, P., Langer, R., "Photoencapsulation of chondrocytes in poly(ethylene oxide)-based semi-interpenetrating networks", Journal of Biomedical Materials Research, 2000, 51 (2): 164-171                   | X              |
|                    |                       | Ward, J.H., Peppas, N.A., "Preparation of controlled release systems by free-radical UV polymerizations in the presence of a drug", Journal of Controlled Release, 2001, 71 (2): 183-192  | X              |
|                    |                       | Scott, R.A., Peppas, N.A., "Highly crosslinked, PEG-containing copolymers for sustained solute delivery", Biomaterials, 1999, 20 (15): 1371-1380  | X              |
|                    |                       | Podual, K., Doyle F.J., Peppas N.A., "Preparation and dynamic response of cationic copolymer hydrogels containing glucose oxidase", Polymer, 2000, 41 (11): 3975-3983   | X              |
|                    |                       | Colombo, P., Bettini, R., Peppas, N.A., "Observation of swelling process and diffusion front position during swelling in hydroxypropyl methyl cellulose (HPMC) matrices containing a soluble drug", Journal of Controlled Release, 1999, 61 (1,2): 83-91        | X              |
|                    |                       | Ende, M.T.A., Peppas, N.A., "Transport of ionizable drugs and proteins in crosslinked poly(acrylic acid) and poly(acrylic acid-co-2-hydroxyethyl methacrylate) hydrogels. 2. Diffusion and release studies", Journal of Controlled Release, 1997, 48 (1): 47-56 | X              |
| /C.H./             |                       | Graziacascione, M., Zhu, Z., Borselli, F., Lazzeri, L., "Poly(vinyl alcohol) hydrogels as hydrophilic matrices for the release of lipophilic drugs loaded in PLGA nanoparticles", Journal of Material Science: Materials in Medicine, 2002, 13: 29-32           | X              |

|                    |                  |                 |            |
|--------------------|------------------|-----------------|------------|
| Examiner Signature | /Casey Hagopian/ | Date Considered | 04/10/2008 |
|--------------------|------------------|-----------------|------------|

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard St.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. This information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Please type a plus sign (+) inside this box ➡



PTO/SB/08A (08-03)

Approved for use through 07/31/2006. OMB 0651-0031  
 U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

|   |                        |                      |                |
|---|------------------------|----------------------|----------------|
| Substitute for form 1449A/PTO   |                        | Complete if Known    |                |
| <b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br>(use as many sheets as necessary) |                        | Application Number   | 10/802,058     |
|   |                        | Filing Date          | March 17, 2004 |
|   |                        | First Named Inventor | CHAUHAN, ANUJ  |
|   |                        | Art Unit             | 1615           |
|   |                        | Examiner Name        | HAGOPIAN, C.   |
| Sheet 4 of 4  | Attorney Docket Number | T2315-908542US02     |                |

## OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

| Examiner Initials* | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T <sup>2</sup> |
|--------------------|-----------------------|---|----------------|
| /C.H./             |                       | Mandell, R.B., "Contact Lens Practice: Hard and Flexible Lenses", 2 <sup>nd</sup> ed., Charles C. Thomas, Springfield, vol. 3, 1974   | X              |
| /C.H./             |                       | Creech, J.L., Chauhan, A., Radke, C.J., "Dispersive mixing in the posterior tear film under a soft contact lens", I&EC Research, 2001, 40: 3015-3026  | X              |
| /C.H./             |                       | McNamara, N.A., Polse, K.A., Brand, R.D., Graham, A.D., Chan, J.S., McKenney, C.D., "Tear mixing under a soft contact lens: Effects of lens diameter". Am. J. of Ophth., 1999, 127(6): 659-65   | X              |
| /C.H./             |                       | Arriagada, F.J., Osseo-Asare, K., "Synthesis of nanosize silica in a nonionic water-in-oil microemulsion: effects of the water/surfactant molar ratio and ammonia concentration", Journal of Colloid & Interface Science 1999, 211: 210-220]                    | X              |
|                    |                       |   |                |
|                    |                       |   |                |
|                    |                       |   |                |
|                    |                       |   |                |

|                    |                  |                 |            |
|--------------------|------------------|-----------------|------------|
| Examiner Signature | /Casey Hagopian/ | Date Considered | 04/10/2008 |
|--------------------|------------------|-----------------|------------|

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard St.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. This information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.